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# 510(k) Summary of Safety and Effectiveness

**SAFE MEDICAL DEVICES ACT OF 1990**
510(k) Summary

**NAME OF FIRM:** I.T.S. GmbH
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**510(k) FIRM CONTACT:** Al Lippincott
Engineering Consulting Services, Inc.
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Prior Lake, MN 55372
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**DATE:** August 31, 2013

**TRADE NAME:** **I.T.S. IM Nail Systems CFN-CTN-CHN**

**COMMON NAME:** Femoral, Tibial and Humeral – Intramedullary Nail

**CLASSIFICATION:** Rod, Fixation, Intramedullary and Accessories;
Screw, Fixation, Bone;
Nail, Fixation, Bone;
Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component

Intramedullary fixation rod (*See 21 CFR, Sec. 888.*3020).
Smooth or threaded metallic bone fixation fastener (*See 21CFR, Sec. 888.3040*).
Single/multiple component metallic bone fixation applieances and accessories (*See 21 CRF, Sec. 888.3030*).

**DEVICE PRODUCT CODE:** **HSB**

**SUBSEQUENT PRODUCT CODE:** **HWC, JDS, KTT**

**SUBSTANTIALLY EQUIVALENT DEVICES**
Synthes – Proximal Femoral (PFN) & Cannulated Femoral Nail (CFN) Systems (**K970097, K954856**)
Zimmer – Sirus IM Femur Nail System (**K093270**)
Stryker - T2 RECON Nail System (**K032898, K051624, K102992**)
Biomet – Femoral Locking Nail System (**K072161**)
Synthes – Ti Cannulated Tibial Nail (CTN) System (**K962047**)
Zimmer – Sirus IM Tibia Nail System (**K093270, K082770**)
Stryker – T2 Tibial Nailing System (**K021027,K011622,K003018**)
Biomet – Tibial Locking Nail System (**K063570**)
I.T.S. – CONNEXX Locking Tibia Nail (**K080706**)

I.T.S. – Distal Humeral 3.5mm Cortical Scew (**K080184**)
Synthes – MultiLoc Humeral Nailing System (**K120807**)
Smith & Nephew – TriGen Straight Humeral Nail (**K032722**)
Stryker – T2 Proximal Humeral Nailing System (**K042396**)
Acumed – Polarus Humeral Rod (**K920666, K951673, K951740**)

**DEVICE DESCRIPTION:** The ***I.T.S. IM Nail Systems CFN-CTN-CHN*** consists of Predicate type intramedullary nail trauma implant components commonly found with large companies with orthopedic markets in the United States. These 'Intramedullary (IM) Nail trauma implant devices' consist of the following categories:

1. **CFN – Cannulated Femur Nail System**

2. **CTN – Cannulated Tibia Nail System**

3. **CHN – Cannulated Humeral Nail System**

A brief and concise description of each system is enclosed as follows:

**1. CFN – Cannulated Femur Nail System**: The *I.T.S. CFN – Cannulated Femur Nail System* is a curved/bowed Intramedullary(IM) Nail in a right and left configuration to fit the natural bow of the femur and is inserted proximally/antegrade over 3.5/3.0mm calibrated guide wires. The CFN - IM Nail is composed of various nail diameters in sizes of 9.0, 10.0, 11.0, 12.0 and 13.0mm and various lengths from 240mm to 480mm in 20mm increments. The CFN - IM Nail accepts a 6.5mm Cortical Screw in various lengths for cross-screw fixation in the larger diameter proximal region of the nail and a 4.7mm Triple-lead Cortical Screw in various lengths for cross-screw fixation in the distal portion of the nail. A dynamization slot is located in the distal portion of the nail and an End Cap (in +0, +5, +10, +15, +20, +25 & +30 lengths) is available for proximal closing of the nail. The nail proximal cross-screw insertion uses Insertion Guide instrumentation for location of the hole and screw insertion preparation throught the bone cortex and nail. The nail distal cross-screw insertion uses x-ray fluoroscopic imaging for nail distal hole/slot location.

All CFN - IM Nail, End Cap and Screw components are manufactured from Alloyed 6-4 Titanium material to ASTM F136 and are processed with an anodize DOTIZE surface treatment.

Associated instrumentation such as Insertion Guide accessories, guide pins, drill sleeves, drill guides, drills, screwdriver, depth gauge with removal instruments are available with the system. All CFN – IM Nails, End Caps and Screws are provided **Non-Sterile**.

**2. CTN – Cannulated Tibia Nail System**: The *I.T.S. CTN – Cannulated Tibia Nail System* is a universal straight Intramedullary(IM) Nail with a $5^0$ proximal and distal bend configuration to fit the anatomy of the tibia and is inserted proximally/antegrade over 3.5/3.0mm calibrated guide wires. The CTN – IM Nail is composed of various nail diameters in sizes of 9.0, 10.0, 11.0, and 12.0mm and various lengths from 240mm to 420mm in 15mm increments. The CTN - IM Nail accepts only the 4.7mm Triple-lead Cortical Screw in various lengths for cross-screw fixation in both the proximal/distal portion of the nail. A dynamization slot is located in the proximal portion of the nail and an End Cap (in +0, +5, +10, +15, +20, +25, +30 lengths) is available for proximal closing of the nail. The nail proximal cross-screw insertion uses Insertion Guide instrumentation for location of the hole/slot and screw insertion preparation throught the bone cortex and nail. The nail distal cross-screw insertion uses x-ray fluoroscopic imaging for nail distal hole location.

All CTN - IM Nail, End Cap and Screw components are manufactured from Alloyed 6-4 Titanium material to ASTM F136 and are processed with an anodize DOTIZE surface treatment.

Associated instrumentation such as Insertion Guide accessories, guide pins, drill sleeves, drill guides, drills, screwdriver, depth gauge and removal instruments are available with the system. All CTN – IM Nails, End Caps and Screws are provided **Non-Sterile**.

**3. CHN – Cannulated Humeral Nail System**: The *I.T.S. CHN – Cannulated Humeral Nail System* is a right and left Intramedullary (IM) straight Nail with a $4^0$ proximal bend configuration to fit the anatomy of the humerus and is inserted proximally over 2.0/2.5mm calibrated guide wires. The CHN - IM Nail is composed of various nail diameters in sizes of 7.0, 8.0, and 9.0mm and various lengths from 140mm to 320mm in 10 and 20mm increments. The CHN - IM Nail accepts only a 3.5mm Double-lead Cortical Screw in various lengths for cross-screw fixation in both the proximal/distal portion of the nail. An End Cap (in +0, +5, +10, +15, +20, +25 & +30 lengths) is available for proximal closing of the nail. The nail proximal cross-screw insertion uses Insertion Guide instrumentation for location of the hole and screw insertion preparation throught the bone cortex and nail. The nail distal cross-screw insertion uses x-ray fluoroscopic imaging for nail distal hole location.

All CHN - IM Nail, End Cap and Screw components are manufactured from Alloyed 6-4 Titanium material to ASTM F136 and are processed with an anodize DOTIZE surface treatment.

Associated instrumentation such as Insertion Guide accessories, guide pin, drill sleeves, drill guides, drills, screwdriver, depth gauge and removal instruments are available with the system. All CHN - IM Nails, End Caps and Screws are provided **Non-Sterile**.

**I.T.S. GmbH - 510(k) Summary –**

**INTENDED USE:**

The ***intended use*** of the *I.T.S. IM Nail* Systems CFN-CTN-CHN is to stablilize and fix long bone fractures to facilitate healing in an adult patient and is composed of the following categories:

The *I.T.S. CFN - Cannulated Femur Nail System* **is indicated for use** in long bone femur fracture fixation which include:
Open and closed femur shaft fractures; Intertrochanteric, supracondylar and ipsilateral fractures; High subtrochanteric fractures; Combined inter and subrochanteric fractures; Pertrochanteric fractures; Pseudoarthrosis and correction osteotomy; Non-union, mal-union and delayed union fractures; Pathological fractures, impending pathologic fractures, and tumor resections and; Fractures proximal to a total knee arthroplasty;
The system is not for spinal use.

The *I.T.S. CTN - Cannulated Tibia Nail System* **is indicated for use** in long bone tibia fracture fixation which include:
Proximal, metaphyseal, epiphyseal and distal shaft fractures; Segmental, simple, compound and comminuted fractures; Transverse, oblique and spiral fractures; Surgically created defects using osteotomies,such as for leg length discrepencies or deformity; Pathologic fractures; Pseudoarthrosis, non-union, mal-union and delayed union of the tibia; Fractures involving osteopenic and osteoporotic bone; Open fractures of the tibia and; Reconstruction of the tibia after tumor resection and/or bone loss.
The system is not for spinal use.

The *I.T.S. CHN - Cannulated Humeral Nail System* **is indicated for use** in long bone humerus fracture fixation which include:
Dislocated, unstable 2, 3 and 4 part fractures of the proximal humerus; Valgus-impacted 4 part fractures of the proximal humerus; Proximal humeral fractures with diaphyseal extension into the shaft; Pseudoarthrosis, non-unions, mal-unions and malalignments of the proximal humerus and; Pathological and impending pathological fractures.
The system is not for spinal use.

**EQUIVALENCE:**

The I.T.S. IM Nail Systems CFN-CTN-CHN are Substantially Equivalent(SE) to the various predicate IM Nail, End Cap and Screw Systems as listed. No nonclinical testing was used in the determination of substantial equivalence.

**SUMMARY OF TECHNOLOGICAL CHARACTERISTICS**

The I.T.S. IM Nail Systems CFN-CTN-CHN are Similar in Material, Geometry Design/Markings, and Indications to predicate system(s) currently sold in the U.S. market.

**SUMMARY OF SAFETY AND EFFECTIVENESS:**

The I.T.S. IM Nail Systems CFN-CTN-CHN are shown to be safe and effective for use in long bone fracture stablization and fixation in the femur, tibia and humerus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 7, 2014

I.T.S. GmbH
% Mr. Al Lippincott
U.S Agent and Official Correspondent for I.T.S. GmbH
Engineering Consulting Services, Inc.
3150 E. 200th Street
Prior Lake, Minnesota 55372

Re: K132945
Trade/Device Name: I.T.S. IM Nail Systems CFN-CTN-CHN
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Codes: HSB, HWC, JDS, KTT
Dated: December 16, 2013
Received: December 20, 2013

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE

510(k) NUMBER: K132945

DEVICE NAME: **I.T.S. IM Nail Systems CFN-CTN-CHN**

The ***intended use*** of the *I.T.S. IM Nail* Systems is to stablilize and fix long bone fractures to facilitate healing in an adult patient and is composed of the following categories:

The *I.T.S. CFN - Cannulated Femur Nail System* **is indicated for use** in long bone femur fracture fixation which include:
Open and closed femur shaft fractures; Intertrochanteric, supracondylar and ipsilateral fractures; High subtrochanteric fractures; Combined inter and subrochanteric fractures; Pertrochanteric fractures; Pseudoarthrosis and correction osteotomy; Non-union, mal-union and delayed union fractures; Pathological fractures, impending pathologic fractures, and tumor resections and; Fractures proximal to a total knee arthroplasty;
The system is not for spinal use.

The *I.T.S. CTN - Cannulated Tibia Nail System* **is indicated for use** in long bone tibia fracture fixation which include:
Proximal, metaphyseal, epiphyseal and distal shaft fractures; Segmental, simple, compound and comminuted fractures; Transverse, oblique and spiral fractures; Surgically created defects using osteotomies,such as for leg length discrepencies or deformity; Pathologic fractures; Pseudoarthrosis, non-union, mal-union and delayed union of the tibia; Fractures involving osteopenic and osteoporotic bone; Open fractures of the tibia and; Reconstruction of the tibia after tumor resection and/or bone loss.
The system is not for spinal use.

The *I.T.S. CHN - Cannulated Humeral Nail System* **is indicated for use** in long bone humerus fracture fixation which include:
Dislocated, unstable 2, 3 and 4 part fractures of the proximal humerus; Valgus-impacted 4 part fractures of the proximal humerus; Proximal humeral fractures with diaphyseal extension into the shaft; Pseudoarthrosis, non-unions, mal-unions and malalignments of the proximal humerus and; Pathological and impending pathological fractures.
The system is not for spinal use.

Prescription Use XXXX AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices